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Filed : September 16, 2003

REMARKS

The foregoing amendments and the following remarks are responsive to the April 19, 2007 Office Action. Claims 1, 2, and 4-24 remain pending in the present application. Claims 1, 6, 7, and 16 have been amended and Claims 17-24 were previously withdrawn from consideration. New Claims 25-27 have been added. In response to the Office Action mailed April 19, 2007, Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Claims 1, 4-5, 7-9, and 12-14 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Reed, Jr. (U.S. Patent No. 5,827,530) ("Reed"). Claims 6, 15, and 16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed in view of Meconi *et al.* (U.S. Patent No. 5,770,220) ("Meconi"). Claims 2, 10, and 11 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed.

Applicants respectfully traverse the present rejection. However, to expedite the prosecution of the present application, Applicants have amended Claims 1, 6, 7, and 16. Applicants expressly reserve the right to further prosecute the original version of any Claims through continuation practice.

Claims 1, 4-5

Claim 1 has been amended to distinctly claim a fluid inlet adapted to selectively secure a connector of a supply of fluid in both the radial and axial direction, as is disclosed in the original specification. This not only allows the fluid medication delivery device to be connected to a supply of fluid without the use of a hypodermic needle, but it also allows the fluid medication delivery device to be securely connected to a replenishable supply of fluid for extended periods of time without the risk of disconnection and for the continuous flow of fluid into the fluid medication delivery device.

In contrast, Reed discloses a fillable patch comprising a loading port 32 having a rubber septum through which medication can be injected by a hypodermic needle. This arrangement is suited for a manual filling operation, as opposed to a continuous filling operation as permitted by the present invention. In particular, neither the loading port 32 nor the rubber septum secures the

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hypodermic needle in the axial direction to permit a long-term connection of fluid to the fillable patch. Nor does Reed disclose such a capability for a continual connection.

For at least this reason, Applicants submit that Reed fails to disclose each and every element recited by amended Claim 1. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 1 and pass this claim to allowance.

Additionally, Applicants submit that Claims 4-5 also define over the cited reference, not only because they depend from Claim 1, but also on their own merit. The fluid medication delivery device of Claim 4 further comprises at least one internal wall within said fluid reservoir, said internal wall segmenting said fluid reservoir into multiple regions interconnected with one another. Applicants respectfully disagree that Reed discloses such a limitation. Feature 40 of Reed's fillable patch is not a segmenting element that defines a separate space in the reservoir as Examiner has stated. In contrast, as shown in Figure 2 and described at column 4, lines 8-24, feature 40 is a "shield" that is intended merely to protect the diffusion membrane 16 from inadvertent damage imparted by the needle used to fill the fillable reservoir 24. Nowhere does Reed disclose that shield 40, or any other feature for that matter, creates an internal wall segmenting the reservoir into multiple regions as the limitation of Claim 4 of the present invention does. Neither is this conclusion indirectly supportable by Reed. In fact, Reed states at column 4, lines 21-24, that the shield 40 may be "free floating within fillable reservoir 24" and "of such size such that loading needle 38 is prevented from piercing diffusion membrane 16." Further, as shown in Figure 2, the projected surface area of shield 40 is only a small fraction of the projected surface area of the outer side 26 or skin side 28 of the fillable reservoir 24, too small to create a useful region even if this were its intended function. Figure 2 also makes clear that shield 40 is merely for protecting the diffusion membrane 16 from puncture holes from the needle.

Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 4-5 and pass these claims to allowance.

Claims 7-9 and 12-14

In contrast with Reed, Claim 7 claims a fluid medication delivery device comprising (among other things) a fluid impermeable pouch having second walls that includes a plurality of

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openings therethrough defining a diffusion area of said delivery device. Reed does not disclose a wall having a single opening therethrough, much less a plurality of openings therethrough, for diffusion.

Further, Claim 7 has been amended to distinctly claim a fluid inlet adapted to selectively secure a connector of a supply of fluid in both the radial and axial direction, as is disclosed in the original specification. This not only allows the fluid medication delivery device to be connected to a supply of fluid without the use of a hypodermic needle, but it also allows the fluid medication delivery device to be securely connected to a replenishable supply of fluid for extended periods of time without the risk of disconnection and for the continuous flow of fluid into the fluid medication delivery device.

In contrast, Reed discloses a fillable patch comprising a loading port 32 having a rubber septum through which medication can be injected by a hypodermic needle. This arrangement is suited for a manual filling operation, as opposed to a continuous filling operation permitted by the present invention. In particular, neither the loading port 32 nor the rubber septum secures the hypodermic needle in the axial direction to permit a long-term connection of fluid to the fillable patch. Nor does Reed disclose such a capability for a continual connection.

For at least these reasons, Applicants submit that Reed fails to disclose each and every element recited by amended Claim 7. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claim 7 and pass this claim to allowance.

Additionally, Applicants submit that Claims 8, 9, and 12-14 also define over the cited reference, not only because they depend from Claim 7, but also on their own merit.

The fluid medication delivery device of Claim 13 further comprises at least one internal wall within said fluid reservoir, said internal wall segmenting said fluid reservoir into multiple regions interconnected with one another. Applicants respectfully disagree that Reed discloses such a limitation. Feature 40 of Reed's fillable patch is not a segmenting element that defines a separate space in the reservoir as Examiner has stated. In contrast, as shown in Figure 2 and described at column 4, lines 8-24, feature 40 is a "shield" that is intended merely to protect the diffusion membrane 16 from damage imparted by the needle used to fill the fillable reservoir 24. Nowhere does Reed disclose that shield 40, or any other feature for that matter, creates an internal wall segmenting the reservoir into multiple regions as the limitations of Claim 4 of the

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present invention do. Neither is this conclusion indirectly supportable by Reed. In fact, Reed states at column 4, lines 21-24, that the shield 40 may be "free floating within fillable reservoir 24" and "of such size such that loading needle 38 is prevented from piercing diffusion membrane 16." Further, as shown in Figure 2, the projected surface area of shield 40 is only a small fraction of the projected surface area of the outer side 26 or skin side 28 of the fillable reservoir 24, too small to create a useful region even if this were its intended function. Figure 2 also makes clear that shield 40 is merely for protecting the diffusion membrane 16 from puncture holes from the needle.

Accordingly, Applicants respectfully request the Examiner withdraw the rejection of 8, 9, and 12-14 and pass these claims to allowance.

Claims 6, and 15-16

Claims 6, 15, and 16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed in view of Meconi *et al.* (U.S. Patent No. 5,770,220) ("Meconi"). Applicants respectfully traverse the present rejection.

Applicants submit that Claims 6, and 15-16 also define over the cited references, not only because they depend from Claim 7, but also on their own merit. Claims 1, from which Claim 6 depends, and 7, from which Claims 15 and 16 depend, claim a delivery device comprising a fluid inlet adapted to selectively secure a connector of a supply of fluid in both the radial and axial direction. As stated above, this dispenses with the need for a hypodermic needle and allowing the connection of the delivery device to a replenishable supply of fluid for extended periods of time without the risk of disconnection and for the continuous flow of fluid into the fluid medication delivery device. Meconi fails to rectify the failure of Reed to disclose, among other elements, the elements listed in amended Claim 1 and Claim 7 as stated above.

Furthermore, Meconi fails to disclose the use of polysulfone, polyethersulfone, polyvinylidene diflouride, or nylon for a semi-permeable layer, as Examiner has stated. To expedite prosecution, Applicants have amended Claim 6 and Claim 16 to omit the materials that are referenced in Meconi.

Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 6, 15 and 16 and pass these claims to allowance.

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Claims 6, and 15-16:

Claims 2, 10, and 11 stand rejected under 35 U.S.C. § 103(a) as being obvious over Reed. Applicants respectfully traverse the present rejection. Claims 2 and 10-11 are not obvious over Reed. The Examiner argues that Reed discloses the claimed inventions except for specific material dimensions. As explained above, Reed fails to disclose the fluid medication delivery device recited by Claims 1 and 7.

Claim 2 depends from amended Claim 1. Claims 10 and 11 depend from Claim 7. Applicants submit that Claims 2, 10, and 11 define over the cited reference not only because they depend from Claims 1 and 7, but also on their own merit. Accordingly, Applicants respectfully request the Examiner withdraw the rejection of Claims 2, 10, and 11, and pass these claims to allowance.

New Claims Have Been Added

New Claims 25-27 have been added. These claims are fully supported by the application as filed. Accordingly, no new matter has been introduced by this Amendment. Furthermore, Claims 25-27 depend from allowable Claim 1 and are allowable for at least the same reasons. In addition, Claims 25-27 are allowable on their own merit. Consideration and allowance of new Claims 25-27 are respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history

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shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

SUMMARY

For the reasons described above, Applicants respectfully request the Examiner withdraw the rejection of the claims and pass Claims 1, 2, and 4-16 to allowance.

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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